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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,809	03/30/2004	Jeffrey Hutterer		6034

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STEVEN HOROWITZ, ESQ.
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SUITE 700
NEW YORK, NY 10017

EXAMINER

CARTER, KENDRA D

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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12/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,809	HUTTERER, JEFFREY	
	Examiner	Art Unit	
	Kendra D. Carter	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 12-20 and 26-39 is/are pending in the application.
- 4a) Of the above claim(s) 36-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 12-20 and 26-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/3/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group 1, claims 1-35, in the reply filed on October 31, 2007 is acknowledged.

Claims 36-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made without traverse. Thus the restriction requirement is made FINAL.

Claims 7-11 and 21-25 are cancelled. Claims 1-6, 12-20 and 26-35 are examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 12-20 and 26-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. (US 5,750,141), in view of Glasser (US 3,212,970), in view of McCadden (US 6,479,058 B1), in view of O'Kane et al. (The Physican and sportsmedicine, September 1999, vol. 27(9), pp. 1-14) in further view of Healthchemist (online pharmacy printout or Naphcon being sold).

Roberts et al. teach a method of topical and/or transdermal administration of a vaso-active agent administered in combination with a therapeutic agent which is useful in treatment of the dermis epidermis, wherein the therapeutic agent may be administered in a similar manner in combination with the vaso-active agent or may be administered separately so as to increase local perfusion and/or concentration of the therapeutic agent at the administration site of the vaso-active agent (see abstract and claim 1; addresses claims 1 and 27). The composition may also include a suitable vehicle or carrier (see column 6, lines 35-36). Therapeutic agents include corticosteroids such as hydrocortisone and dexamethasone (see column 6, lines 39, 40, 49, 53, 54 and 55; addresses 1, 6, 20, 27, 29-34). Suitable vasoconstrictors include naphazoline and phenylephrine hydrochloride (see column 7, lines 33, 41, 42 and 43; addresses claims 1, 3-5, 14-19 and 27).

Roberts et al. does not teach pheniramine maleate or the amounts of the combination solution (claims 1, 2, 3, 4, 5, 13-19, 27 and 28), or the amounts of the

corticosteroid cream (claims 13 and 27), specifically a 1% cream of hydrocortisone (claims 12, 26 and 35).

Glasser teaches the treatment of psoriasis comprising administering any antihistaminic compound, such as pheniramine maleate (see title and column 1, lines 53-54 and 66).

McCadden teach a composition for the topical treatment of skin eruptions from psoriasis (see title and column 1, lines 19 and 20) comprising a corticosteroid of appropriate potency for the condition being treated (see column 2, lines 50-53) in the form of a cream (see column 2, last line). Low potency steroids are generally preferred in view of certain disadvantages of high potency steroids such as hydrocortisone, most preferably from about 0.5 to about 2.5% (see column 4, lines 63-65 and column 5, lines 8-10). The composition is applied topically to the involved area until it has healed (see column 10, lines 11-12).

O'Kane et al. teach topical vasoconstrictors for the treatment of allergic conjunctivitis including the application of 1 drop of a 0.1% solution of Naphazoline HCl and pheniramine maleate, also known as Naphcon-A (see page 5, table 2, see page 6, topical vasoconstrictors, third entry).

Healthchemist teaches that the Naphcon-A product comprising 0.25 mg/ml of naphazoline hydrochloride and 3 mg/ml of pheniramine maleate (see active ingredients).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method steps and composition of Roberts et al. and the combination of pheniramine maleate with either naphazoline HCl or phenylephrine HCl because of the following teachings: (1) Glasser teaches the treatment of psoriasis comprising administering any antihistaminic compound, such as pheniramine maleate (see title and column 1, lines 53-54 and 66); and (2) "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method steps and composition of Roberts et al. in view of Glasser and the specific 1% cream of hydrocortisone (claims 12, 26 and 35) because McCadden teach a composition for the topical treatment of skin eruptions from

psoriasis (see title and column 1, lines 19 and 20) comprising from about 0.5 to about 2.5% of the hydrocortisone cream (see column 2, lines 50-53; column 2, last line; column 4, lines 63-65 and column 5, lines 8-10). Thus, psoriasis is effectively treated with a 1% hydrocortisone cream. Therefore, one would be motivated to use this concentration of hydrocortisone for the method of Roberts et al. in view of Glasser.

In regards to the actual amount of cream applied as disclosed in applicant's claims 13 and 27, it would be obvious to apply approximately 0.05 grams to approximately 0.2 grams because McCadden teaches that the hydrocortisone composition is applied topically to the involved area until it has healed (see column 10, lines 11-12). Thus, the amount to cover the area can comprise approximately 0.05 grams to approximately 0.2 grams, depending on the size of the area to be treated.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method steps and composition of Roberts et al. in view of Glasser and the amounts of the combination solution (claims 1, 2, 3, 4, 5, 13-19, 27 and 28) because of the following teachings: (1) O'Kane et al. teach topical vasoconstrictors for the treatment of allergic conjunctivitis including the application of 1 drop of a 0.1% solution of Naphazoline HCl and pheniramine maleate, also known as Naphcon-A (see page 5, table 2, see page 6, topical vasoconstrictors, third entry); (2) Healthchemist teaches that the Naphcon-A product comprising 0.25 mg/ml of naphazoline hydrochloride and 3 mg/ml of pheniramine maleate (see active

ingredients); and (3) It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) (“[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art.” See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003). Thus, a combination of a decongestant and an antihistamine is known in the applicant's disclosed ratios and applied in the amounts of a volume of at least approximately 0.02 ml (1 to 2 drops). One skilled in the art can determine the amount needed to treat the affected area.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone

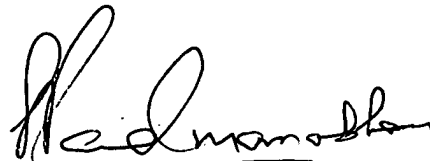
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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC

A handwritten signature in black ink, appearing to read 'Sreeni Padmanabhan', is written over a horizontal line.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER